AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Canceled)

2. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of peptide hormones and hormone derivatives, physiologically active lymphokines and monokines, peptidic enzymes, proteic vaccines, peptidic toxoids, and personalized proteins derived from genoma, in a form suitable for nasal administration.

3. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the peptide hormones and hormone derivatives buserelin, desmopressin, vasopressin, angiotensin, felypressin, octreotide, somatropin, thyrotropin (TSH), somatostatin, gosereline, thryptorelin and insulin (selected from the group consisting of ~~caw~~ cow and pig, synthetic, and recombinant).

4. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt

or its peptidic fragment is selected from the group consisting of the peptide hormones and hormone derivatives protirelin, adrenocorticotropin (ACTH), prolactin, luteinizing hormone (LH), luteinizing hormone-release hormone (LH-RH), leuprorelin, calcitonin (selected from the group consisting of human, chicken, eel, porcine and recombinant), carbocalcitonin and calcitonin gene related peptides (CGRP).

5. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the peptide hormones and hormone derivatives kallikrein, parathyrin, glucagon, oxytocin, gastrin, secretin, leptin, nafarelin, serum gonadotropin, gonadotropin release factor, growth hormone, erytropoietin, hirudin, urograstrone, renin and human parathyroid hormone (h-PTH).

6. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the physiologically active lymphokines and monokines interferon, interleukin, transferrin, histaglobulin, macrocortine, endorphins, enkephalins and neurotensin.

7. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the peptidic enzymes lysozyme, urokinase and superoxide dismutase.

8. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the proteic vaccines acellular and cellular pertussis, diphtheria, tetanus and influenza vaccines.

9. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group consisting of the peptidic toxoids diphtheria, and tetanus and the personalized proteins derived from genoma.

10. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in a concentration of 0.001 microgram/ml to 50.0 mg/ml or of 10 Units/ml to 20000 Units/ml, in relation to the therapeutically effective dose for administration by the endonasal route; and (2) THAM is in a ~~combination~~ concentration of ~~0.5~~ from above 4.0 mg/ml to 30.0 mg/ml.

11. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in a concentration of 0.01 microgram/ml to 50.0 mg/ml or of 20 Units/ml to 12500

Units/ml; and (2) THAM is in a concentration of ~~2.0~~ from above 4.0 mg/ml to 10.0 mg/ml.

12. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in a concentration of 0.05 microgram/ml to 10.0 mg/ml or of 100 Units/ml to 6000 Units/ml; and (2) THAM is in a concentration of ~~2.5~~ 4.15 mg/ml to 4.5 mg/ml.

13. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, wherein said pharmaceutical formulation is in the form of ready-to-use or of reconstituted solution suitable for nasal administration in the form of a drop type or of a nasal spray.

14. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, for administration in a metered single dose volume or in multiple doses thereof, each actuation comprising a metered dose volume between 50 microliters and 200 microliters.

15. (Currently Amended) A ~~method for producing a~~ pharmaceutical ~~formulation~~ composition according to ~~claim 1~~ claim 28, wherein the aqueous liquid diluent or carrier comprises the pharmaceutically acceptable auxiliary additive (a) hydrochloric or citric acid; (b) one or a mixture of methyl or/and propyl p-hydroxybenzoate; and/or (c) cysteine.

16. (Currently Amended) The ~~method~~ pharmaceutical composition according to claim 15, wherein the pharmaceutically acceptable, aqueous liquid diluent or carrier further comprises the pharmaceutically acceptable additive (a) hydrochloric acid 0.1 N in a concentration of 0.3 mg/ml to 50.0 mg/ml or citric acid in a concentration of 0.6 mg/ml to 60.0 mg/ml; (b) one or a mixture of methyl or/and propyl p-hydroxybenzoate in a concentration not exceeding 0.3 mg/ml with a ratio of 2:1 to 20:1; and (c) cysteine in a concentration of 0.5 mg/ml to 10.0 mg/ml.

17. (Currently Amended) ~~A~~ The method ~~for producing a pharmaceutical formulation for nasal administration~~ according to ~~claim 1~~ claim 34, wherein said nasal composition is in the form of a ready-to-use solution, and wherein said method ~~comprising~~ comprises the steps of: adding an adequate amount of distilled water to THAM, and optionally to methyl or/and propyl p-hydroxybenzoate, hydrochloric or citric acid and cysteine until complete dissolution; and then dissolving at the end the ~~adequate quantity of~~ nasal peptide or its pharmaceutically acceptable salt or its peptidic fragment in the solution mixture.

18. (Previously Presented) The method according to claim 17, which further comprises the step of: filtering to make the solution suitable for nasal administration and filling a mono-disposable, or multidose device system with the filtrate, more preferably with a progressive dose counting system.

19. (Currently Amended) ~~A~~ The method ~~for producing a pharmaceutical formulation for nasal administration,~~ according to ~~claim 1,~~ claim 34, wherein said nasal composition is in the form of reconstituted solution, and wherein said method ~~comprising~~ comprises:

preparing a first container ~~no. 1~~ with the nasal peptide either by dosing in the container the corresponding weight of powder of active nasal peptide or by preparing a suitable solution with a known concentration of the same, pouring the individually dosed volume into the container and then lyophilizing it to yield a lyophilized powder;

preparing a second container ~~no. 2~~ comprising the solvent mixture for reconstitution, resulting from adding an adequate amount of distilled water to THAM, and optionally to methyl or/and propyl p-hydroxybenzoate, hydrochloric or citric acid and cysteine until complete dissolution;

filtering to make the solution suitable for nasal administration; and

filling the second container ~~no. 2~~ with the filtrate.

20. (Currently Amended) The method according to claim 19, wherein the first container ~~no. 1~~ is prepared by dosing directly in the container the corresponding weight of active nasal peptide powder, or by preparing a suitable solution with a known concentration of the same, pouring the individually dosed volume directly into the container and then lyophilizing it directly in the container to yield a lyophilized powder.

21. (Currently Amended) The method according to claim 19, which further comprises the step of: preparing the reconstituted solution at the time of starting its

use by pouring the solvent mixture of the second container ~~no. 2~~ into the first container ~~no. 1~~; mixing thoroughly by rotation until complete dissolution; and screwing the multidose device system on the neck of the first container ~~no. 1~~, comprising the reconstituted solution.

22. (Currently Amended) The pharmaceutical ~~formulation,~~ composition according to ~~claim 1~~ claim 28, having a long shelf life~~, and when in use providing compositions of a therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment~~.

23. (Currently Amended) ~~A~~ The method ~~for treating a patient which comprises~~ according to claim 35, comprising intranasally administering a dosed volume of said nasal composition in the form of drop type or of nasal spray to ~~said~~ a patient, ~~a dosed volume of a formulation according to claim 1,~~ to elicit the desired pharmacological effect.

24. (Currently Amended) The method according to claim 23, in which the administrable dose volume of the ~~pharmaceutical formulation~~ nasal composition, comprised in a metered monodose disposable or in a multidose system thereof, ~~is comprised~~ comprises between 50 microliters and 200 microliters per actuation.

25. (Currently Amended) The ~~method~~ composition according to claim 16, wherein (a) is citric acid in a concentration of 2.8 mg/ml to 6.2 mg/ml.

26. (New) A nasally administrable pharmaceutical composition for reversibly depolarizing the nasal mucosa epithelial cells comprising: (a) a therapeutically effective amount of a pharmacologically active nasal peptide or pharmacologically active salt thereof or pharmacologically active fragment thereof; and (b) as a selective absorbefacient, THAM [tris(hydroxymethyl)aminomethane], in an amount effective to selectively enhance the permeability and improve the efficiency of active absorption of said peptide or salt or fragment through the nasal mucosa epithelial cells, said amount being from above 4.0 mg/ml to 30.0 mg/ml; in a pharmaceutically acceptable, aqueous liquid diluent or carrier therefor, said composition being in a form suitable for nasal administration.

27. (New) A nasally administrable pharmaceutical composition for reversibly depolarizing the nasal mucosa epithelial cells comprising: (a) a therapeutically effective amount of a pharmacologically active nasal peptide or pharmacologically active salt thereof or pharmacologically active fragment thereof; and (b) as a selective absorbefacient, THAM [tris(hydroxymethyl)aminomethane], in an amount effective to selectively enhance the permeability and improve the efficiency of active absorption of said peptide or salt or fragment through the nasal mucosa epithelial cells; in a pharmaceutically acceptable, aqueous liquid diluent or carrier therefor, said composition being non-isotonic, said composition being in a form suitable for nasal administration.

28. (New) A nasally administrable pharmaceutical composition for reversibly depolarizing the nasal mucosa epithelial cells comprising: (a) a therapeutically

effective amount of a pharmacologically active nasal peptide or pharmacologically active salt thereof or pharmacologically active fragment thereof; and (b) as a selective absorbefacient, THAM [tris(hydroxymethyl)aminomethane], in an amount effective to selectively enhance the permeability and improve the efficiency of active absorption of said peptide or salt or fragment through the nasal mucosa epithelial cells; in a pharmaceutically acceptable, aqueous liquid diluent or carrier therefor, said composition being devoid of methylcellulose, crospovidone, povidone and any similar viscosity modifying agents, said composition being in a form suitable for nasal administration.

29. (New) The pharmaceutical composition according to claim 28, said composition being non-isotonic.

30. (New) The pharmaceutical composition according to claim 26, wherein the amount of THAM is from above 4.0 mg/ml to 10.0 mg/ml.

31. (New) The pharmaceutical composition according to claim 26, wherein the amount of THAM is from about 4.15 mg/ml to about 5.8 mg/ml.

32. (New) The pharmaceutical composition according to claim 28, wherein the amount of THAM is from about 4.15 mg/ml to about 5.8 mg/ml.

33. (New) The pharmaceutical composition according to claim 29, wherein the amount of THAM is from about 4.15 mg/ml to about 5.8 mg/ml.

34. (New) A method for imparting to a nasal composition the ability to reversibly depolarize the nasal mucosa epithelial cells, and selectively enhance the permeability and improve the efficiency of active absorption of a pharmacologically active nasal peptide or pharmacologically active salt thereof or pharmacologically active fragment thereof through the nasal mucosa epithelial cells, said method comprising formulating into a nasal composition a therapeutically effective amount of said peptide or salt or fragment together with THAM [tris(hydroxymethyl)aminomethane], as a selective absorbefacient, in an amount effective to selectively enhance the permeability and improve the efficiency of active absorption of said peptide or salt or fragment through the nasal mucosa epithelial cells, in a pharmaceutically acceptable, aqueous liquid diluent or carrier therefor.

35. (New) A method for reversibly depolarizing the nasal mucosa epithelial cells, and selectively enhancing the permeability and improving the efficiency of active absorption of a pharmacologically active nasal peptide or pharmacologically active salt thereof or pharmacologically active fragment thereof through the nasal mucosa epithelial cells, said method comprising combining into a nasal composition and nasally administering to a subject in need thereof a therapeutically effective amount of said peptide or salt or fragment together with THAM [tris(hydroxymethyl)aminomethane], as a selective absorbefacient, in an amount effective to selectively enhance the permeability and improve the efficiency of active absorption of said peptide or salt or fragment through the nasal mucosa epithelial cells, in a pharmaceutically acceptable, aqueous liquid diluent or carrier therefor, formulated for nasal administration.

36. (New) The method according to Claim 34, wherein the nasal composition is formulated to be non-isotonic.

37. (New) The method according to Claim 34, wherein the nasal composition is formulated to be devoid of methylcellulose, crospovidone, povidone and any similar viscosity modifying agents.

38. (New) The method according to Claim 37, wherein the nasal composition is formulated to be non-isotonic.

39. (New) The method according to Claim 35, wherein the nasal composition is formulated to be non-isotonic.

40. (New) The method according to Claim 35, wherein the nasal composition is formulated to be devoid of methylcellulose, crospovidone, povidone and any similar viscosity modifying agents.

41. (New) The method according to Claim 40, wherein the nasal composition is formulated to be non-isotonic.